

company announcement

Tresiba® and Ryzodeg® receive marketing authorisations in Europe

Bagsværd, Denmark, 21 January 2013 – Novo Nordisk today announced that the European Commission has granted marketing authorisations for Tresiba® (insulin degludec) and Ryzodeg® (insulin degludec/insulin aspart) for the treatment of diabetes in adults. The authorisations cover all 27 European Union member states.

Tresiba®, the brand name for insulin degludec, is a once-daily new-generation basal insulin analogue with an ultra-long duration of action. In 'treat-to-target' studies supporting the new drug application where Tresiba® was compared to insulin glargine, Tresiba® demonstrated a significantly lower risk of overall and nocturnal hypoglycaemia, while successfully achieving equivalent reductions in HbA_{1c}. Further, with a duration of action beyond 42 hours, Tresiba® is the first basal insulin to offer patients the possibility of adjusting the time of injection, when needed.

Ryzodeg®, the brand name for insulin degludec/insulin aspart, contains the new-generation once-daily basal insulin degludec in a soluble formulation with insulin aspart. Ryzodeg® can be administered once or twice daily with the main meal(s). In a 'treat-to-target' study supporting the new drug application where Ryzodeg® was compared to NovoMix®, Ryzodeg® demonstrated a significantly lower risk of overall and nocturnal hypoglycaemia while successfully achieving equivalent reductions in HbA_{1c}.

In Europe, Tresiba® and Ryzodeg® will be available in FlexTouch®, Novo Nordisk's latest prefilled insulin pen, which has an easy auto-injector mechanism. Tresiba® will be offered in two concentrations enabling maximum doses of 80 and 160 units per injection, respectively.

"These marketing authorisations constitute significant milestones for Novo Nordisk and the treatment of diabetes," says Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "We look forward to making Tresiba® and Ryzodeg® available to many people with diabetes in Europe."

Novo Nordisk expects to launch Tresiba® in the UK and Denmark during the first half of 2013 and in other European markets throughout the rest of 2013 and 2014. Ryzodeg® is currently expected to be launched approximately one year after Tresiba®.

About Tresiba® and Ryzodeg®

Tresiba® is the global brand name for insulin degludec, a once-daily new-generation basal insulin analogue with an ultra-long duration of action, discovered and developed by Novo Nordisk. Tresiba® has a distinct, slow absorption which provides a flat and stable action profile. Tresiba® has been studied in a large-scale clinical trial programme, BEGIN®, examining its impact on glucose control, hypoglycaemia and the possibility to flexibly adjust Tresiba® dosing time to suit patient needs.

Ryzodeg®, the global brand name for insulin degludec/insulin aspart, contains Tresiba®, a once-daily new-generation basal insulin analogue in a formulation with a bolus boost of NovoRapid®. Ryzodeg® is the first and only soluble insulin combination of Tresiba® and the most prescribed rapid-acting insulin, NovoRapid® (NovoLog® in the US), providing both fasting and post-prandial glucose control.

Tresiba® and Ryzodeg® were submitted to the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) in September 2011 for regulatory review. In addition, applications have been submitted for regulatory approval in Japan, Canada, Switzerland and a range of other countries. Tresiba® and Ryzodeg® were approved in Japan in September and December 2012, respectively. In November 2012, the products received a positive vote for approval from an FDA Advisory Committee in the US.

Novo Nordisk is a global healthcare company with 89 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Headquartered in Denmark, Novo Nordisk employs approximately 33,900 employees in 75 countries, and markets its products in more than 190 countries. Novo Nordisk's B shares are listed on NASDAQ OMX Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com.

Further information

Media:

Mike Rulis	+45 4442 3573	mike@novonordisk.com
Ambre Morley (US)	+1 609 216 5240	abmo@novonordisk.com

Investors:

Kasper Roseeuw Poulsen	+45 4442 4303	krop@novonordisk.com
Frank Daniel Mersebach	+45 4442 0604	fdni@novonordisk.com
Lars Borup Jacobsen	+45 3075 3479	lbpj@novonordisk.com
Jannick Lindegaard (US)	+1 609 786 4575	jlis@novonordisk.com